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PTO/SB/21 (03-03)


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| TRANSMITTAL FORM (to be used for all correspondence after initial filing) | Application Number | 10/720,977 |
| | Filing Date | November 24, 2003 |
| | First Named Inventor | David B. MacLean |
| | Art Unit | 1617 |
| | Examiner Name | |
| Total Number of Pages in This Submission | Attorney Docket Number | PC10842B |

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| Remarks | | |
| SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT | | |
| Firm or Individual | Todd M. Crissey Reg. No. 37,807 | |
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| Sheet | 1 | of | 3 |
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| Examiner Name | |
| Attorney Docket Number | PC10842B |

U. S. PATENT DOCUMENTS

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|-----------------------|---|--------------------------------|---|---|----------------|
| Examiner Initials* | Cite No. ¹ | Foreign Patent/D ocument | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear | T ⁹ |
| | | Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | | | | |
| | | WO 97/24369 | 07-10-1997 | Carpino et al. | | |
| | | WO 98/58947 | 12-30-1998 | Carpino et al. | | |
| | | WO 98/58949 | 12-30-1998 | Carpino et al. | | |
| | | WO 00/12047 | 03-09-2000 | Bach et al. | | |
| | | EP 0 995 748 | 04-26-2000 | Carpino | | |
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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | Complete if Known | | | |
| | | Application Number | 10/720,977 | | |
| | | Filing Date | November 24, 2003 | | |
| | | First Named Inventor | David B. MacLean | | |
| | | Art Unit | 1617 | | |
| | | Examiner Name | | | |
| Sheet | 2 | of | 3 | Attorney Docket Number | PC10842B |

| NON PATENT LITERATURE DOCUMENTS | | | |
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| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| | | SVENSSON et al., "Effects of GH-Releasing Substances on Bone Mass in Adult Female Rats", Bone, 23(5)(Suppl), Abstract F235 from ASBMR/IBMS Joint Meeting (November 1998) | |
| | | REUBEN et al., "Measuring Physical Function in Community-Dwelling Older Persons: A Comparison of Self-Administered, Interviewer-Administered, and Performance-Based Measures", Journal of the American Geriatrics Society, 43:17-23, 1995 | |
| | | CASAVUEVA and DIEGUEZ, "Growth Hormone Secretagogues: Physiological Role and Clinical Utility", TEM, 10(1):30-38, 1999 | |
| | | SVENSSON and BENGTSSON, "Clinical and Experimental Effects of Growth Hormone Secretagogues on Various Organ Systems", Hormone Research, 1999; 51(suppl 3):16-20 | |
| | | SVENSSON et al., "Treatment with the Oral Growth Hormone Secretagogue MK-677 Increases Markers of Bone Formation and Bone Resorption in Obese Young Males", J. Bone Miner. Res., 13(7):1158-1166, 1998 | |
| | | GURALNIK et al., "A Short Physical Performance Battery Assessing Lower Extremity Function: Association with Self-Reported Disability and Prediction of Mortality and Nursing Home Admission", Journal of Gerontology, 49(2):M85-M94, 1994 | |
| | | GURALNIK et al., "Lower-Extremity Function in Persons Over the Age of 70 Years as a Predictor of Subsequent Disability", New England Journal of Medicine, 332:556-561, 1995 | |
| | | JUDGE et al., "Exercise to Improve Gait Velocity in Older Persons", Arch Phys Med Rehabil., 74:400-406, 1993 | |
| | | JUDGE et al., "The Relationship Between Physical Performance Measures and Independence in Instrumental Activities of Daily Living", J Am Geriatr Soc, 44:1332-1341, 1996 | |
| | | ANKERSON et al., "Growth hormone secretagogues: recent advances and applications", Drug Discovery Today, 4(11):497-506, 1999 | |

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| Examiner Signature | | Date Considered | |
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STATEMENT BY APPLICANT**

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| | First Named Inventor | | David B. MacLean | | |
| | Art Unit | | 1617 | | |
| | Examiner Name | | | | |
| Sheet | 3 | of | 3 | Attorney Docket Number | PC10842B |

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|-----------------------|--------------------------|---|----------------|
| | | KOJIMA et al., "Ghrelin is a growth-hormone-releasing acylated peptide from stomach", Nature, 402:656-660, 1999 | |
| | | FIATARONE et al., "Exercise Training and Nutritional Supplementation for Physical Frailty in Very Elderly People", New England Journal of Medicine, 330(25):1769-1775, 1994 | |
| | | TINETTI and GINTER, "Identifying Mobility Dysfunctions in Elderly Patients", Journal of the American Medical Association, 259(8):1190-1193, 1988 | |
| | | TINETTI et al., "Shared Risk Factors for Falls, Incontinence, and Functional Dependence, Unifying the Approach to Geriatric Syndromes", Journal of the American Medical Association, 273(17):1348-1353, 1995 | |
| | | BROSS et al., "Anabolic Interventions for Aging-Associated Sarcopenia", J. Clin. Endocrinol. Metab., 84(10):3420-3430, 1999 | |
| | | SMITH et al., "Peptidomimetic Regulation of Growth Hormone Secretion", Endocrine Reviews, 18(5):621-645, 1997 | |
| | | LIEBER et al., "Growth Hormone Secretagogue Increases Muscle Strength during Remobilization after Canine Hindlimb Immobilization", Journal of Orthopaedic Research, 15:519-527, 1997 | |
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